K002478

OCT - 5 2000

Premarket Notification 510(k) Summary
As required by section 807.92

S/5 Compact Anesthesia Monitor with S-00A05/6 or L-00A07/8 software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

August 9, 2000

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 software

COMMON NAME:

Patient monitor

CLASSIFICATION NAME:

The following Class III classifications appear applicable:
Monitor, Physiological, Patient with Arrhythmia detection or alarms (per 21 CFR 870.1025)
Arrhythmia detector and alarm (per 21 CFR 870.1025)
Monitor, ST segment with Alarm (per 21 CFR 870.1025)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software is substanyially equivalent to the predicate AS/3™ Compact Monitor (K933156), to the AS/3™ Compact Monitor (K933156), AS/3™ Record Keeper (K923172) and the predicate CS/3™ Critical Care Monitor with S-ICU99A software (K000168).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software uses several types of plug-in measurement modules. Modules are the subject of separate 510(k)'s and are not part of this notification

The S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature. Modules are placed in the S/5™ monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can begin.

The S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter.

The S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™. The S/5™ Compact Anesthesia Monitor has a built in color LCD display and also a built in NiMH (Nickel Metal Hydride) battery option.

The keyboard is integrated to the monitor frame. A hand-held Remote controller (REMCO) can also be directly connected to the S/5™ Compact Anesthesia Monitor via a long cord and it provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. Using the recordkeeper software, patient related care events are documented using a separate keyboard, which is also connected to the frame. To facilitate quick access to menus, a bar code reader is available.

The software S-00A05/6 and L-00A07/8 performs some module related tasks like arrhythmia analysis, ST–values calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation, EEG spectrum analysis and evoked potential response averaging. All the module communication is also handled in the main software. Software L-00A07/8 includes the same software as S-00A05/6 respectively and also the option of creating patient care documentation. The trend information is automatically transferred to the anesthetic record, and the related events and medication can be easily entered with the same user interface as the monitor itself.

The S/5™ Compact Anesthesia Monitor can be in a stand-alone or networked configuration. If networked, measurements are sent to the network for central station or monitor-to-monitor viewing. Trends as well as the patient care documentation can be sent via a network to a central computer for archiving.

INTENDED USE as required by 807.92(a)(5)

The S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 is intended for multiparameter patient monitoring with optional patient care documentation.

The S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion and neurophysiological status of all hospital patients.
The S/5™ Compact Anesthesia Monitor with L-00A07, L-00A08 software is also indicated for documenting patient care related information.
The S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software is a modular multiparameter patient monitor providing connections to measurement modules. The general construction of the S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software and intended use are the same as for the predicate AS/3™ Compact Monitor (K933156). However, indications for use are slightly different from the predicates due to the introduction of new measurement modules (parameters) and bedside arrhythmia analysis. These new measurement modules are the subjects of their own separate 510(k) premarket notifications.

The S/5™ Compact Anesthesia Monitor with L-00A07, L-00A08 software is identical in terms of monitoring possibilities to the monitor equipped with S-00A05 or S-00A06. The L-00A07 and L-00A08 software simply extend the capability to document patient care related information. The S/5™ Compact Anesthesia Monitor with L-00A07 and L-00A08 software is thus substantially equivalent to the AS/3™ Compact Monitor (K933156) and AS/3™ Record Keeper (K923172).

The S/5™ Compact Anesthesia Monitor with extended bedside arrhythmia analysis software capability (i.e. S-00A06 or L-00A08 software) is identical to the bedside arrhythmia portion of the predicate CS/3™ Critical Care Monitor with S-ICU99A software (K000168). Both monitors use the same parameter modules.

As demonstrated in the detailed analysis in this submission and supporting documentation in this notification, the Datex-Ohmeda S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 software is as safe and as effective as the predicates:

- AS/3™ Compact Monitor (K933156)
- AS/3™ Record Keeper (K923172) and
- CS/3™ Critical Care Monitor with S-ICU99(A) software (K000168).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software is in compliance with safety standards and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance to the following mandatory and voluntary standards have been made:

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC60529 (1989)/EN 60529 (1991)
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1995/EN 60601-2-30:1995
- IEC 60601-2-34:1994/EN 60601-2-34:1994
- IEC 60601-2-40:1998/EN 60601-2-40:1998
- IEC 60601-1-2(1993)/EN 60601-1-2:(1993)
- IEC 60601-1-4: 1996/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865;1997
- ISO 7767:1997/EN12598:1999
- ISO 11196 (1995) + Corr. 1:1997/EN ISO11196(1997)
- IEC 60601-2-10:1987/HD 395.2.10:1989
- IEC 60601-2-26:1994/EN60601-2-26
- UL 2601-1:1997
- ANSI/AAMI ES-1 (1993)
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the S/5™ Compact Anesthesia Monitor with S-00A05/6 and L-00A07/8 software as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2000

Mr. Joel C. Kent
Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876

Re: K002478
S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 Software
Regulatory Class: III (three)
Product Code: MHX
Dated: August 9, 2000
Received: August 11, 2000

Dear Mr. Kent:

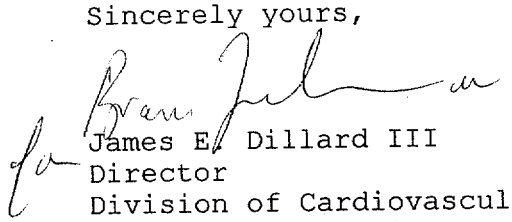
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002478

Device Name: **Datex-Ohmeda S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 software**

The S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion and neurophysiological status of all hospital patients.

The S/5™ Compact Anesthesia Monitor with L-00A07, L-00A08 software is also indicated for documenting patient care related information.

The S/5™ Compact Anesthesia Monitor with S-00A05, S-00A06, L-00A07, L-00A08 software is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002478

Prescription Use____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)